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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,578

04/29/2002

L.Brian Starling

4141-2-PUS

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,578	<b>Applicant(s)</b> STARLING ET AL.	
	<b>Examiner</b> Ruth A. Davis	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 15-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's Request for Continued Examination filed June 22, 2009, IDS filed on August 26, and the amendment and response filed on May 22, 2009 have been received and entered into the case. Claims 1 – 43 are pending; claims 15 – 43 are withdrawn from consideration; claims 1 – 14 have been considered on the merits. All arguments have been full considered.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claim 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Walter et al. (US 5716413) or Jeffries (US 4472840) and further in view of Lemons.

Applicant claims a composition comprising hollow calcium containing microstructures and cancellous bone and/or DBM; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products at about 5 – 95% or 50 – 75% of the composition. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules effective to repair bony defects (p.8). The particles vary in size from about 50  $\mu$ m – 5 mm (p.6).

Radin does not teach the compositions wherein the biologically active molecule is cancellous bone or DBM. However at the time of the claimed invention, both were well known to be effective for repairing bony defects. In support, Walter teaches cancellous bone is used for filling or repairing bone defects (col.2 line 23-25) and Jeffries teaches DBM is useful for repairing bony defects (col.2 line 19-23). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use cancellous bone and/or DBM in the composition of Radin, since they were known in the art to biologically active molecules effective for repairing bony defects as evidenced by the cited references.

Radin does not teach the compositions comprising the claimed amounts of bone mixture. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of

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routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of biologically active molecules in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell of Radin. Furthermore, although Radin does not teach the microstructures comprising each of the claimed calcium materials, it would have been obvious to one of ordinary skill in the art to use any of the claimed materials since they were routinely used in such compositions. In support Lemons teaches compositions comprising calcium particles wherein the particles are made from sintered tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract, col.8 line 65- col.9 line 5). Thus, such materials were well known in the art to be equivalent substitutes used for the same purpose. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to substitute any of the claimed calcium containing materials in the composition of Radin with a reasonable expectation for successfully obtaining an effective calcium shell.

4. Claims 1 – 3 and 7 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Walter or Jefferies, and further in view of Gerhart.

Applicant claims a composition comprising hollow calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof. The composition further comprises a bonding agent that is a polymer selected from

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polyactic acid, polyglycolic acid, polycaprolactone, poly alpha hydroxyl esters, polyphosphatzenes, polyanhydrides and/or polypropylene fumarate; or a bonding agent is a calcium containing cement. The bonding agent is present at about 5 – 75% or 10 – 50% of the composition. The calcium containing cement is calcium phosphate, calcium sulfate or a mixture thereof, specifically calcium sulfate.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules effective to repair bony defects (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the compositions wherein the biologically active molecule is cancellous bone or DBM. However at the time of the claimed invention, both were well known to be effective for repairing bony defects. In support, Walter teaches cancellous bone is used for filling or repairing bone defects (col.2 line 23-25) and Jefferies teaches DBM is useful for repairing bony defects (col.2 line 19-23). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use cancellous bone and/or DBM in the composition of Radin, since they were known in the art to biologically active molecules effective for repairing bony defects as evidenced by the cited references.

Radin does not teach the composition further comprising a bonding agent that is one of the claimed polymers or calcium containing cements, or wherein the cement is present at the claimed amounts. However Radin specifically teaches that the hollow particle compositions are used for filling or repairing bone defects (p.4,9). Gerhart teaches that cements are well known and commonly used in compositions for repairing and fixing bone defects (col.1 line 10-36). Gerhart also teaches compositions for bone repair/fixation comprising calcium phosphate

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particles combined with a cement composition (or bonding agent) and calcium salts.

Specifically, Gerhart teaches that the calcium particles are incorporated with polymers, allowing for superior fixation (col.2 line 22-35). The polymers used include polyesters, polyanhydrides, and/or polypropylene fumarate (col.4 line 35-52, col.5 line 1-8). Gerhart additionally teaches that the cement compositions comprise calcium sulfate or calcium phosphate (col.6 line 40-52).

At the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Gerhart to include the claimed cements or polymers as a bonding agent in the composition of Radin, for its known use in bone repair compositions, and its advantage of superior fixation as disclosed by Gerhart. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Gerhart to include any of the claimed cements or polymers in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell composition of Radin.

While the references do not teach the claimed amounts of cement, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of cement with a reasonable expectation for successfully obtaining the composition obtained by the combined teachings of Radin and Gerhart.

***Response to Arguments***

Applicant argues that the references do not teach demineralized bone matrix or cancellous bone.

However, in light of the newly cited rejections these arguments are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651

August 28, 2009